



NUCLEAR REGULATORY COMMISSION

[Docket No. 50-608; NRC-2022-0180]

In the Matter of SHINE Medical Technologies, LLC

SHINE Medical Isotope Production Facility

AGENCY: Nuclear Regulatory Commission.

ACTION: Order; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) has approved the SHINE Medical Technologies, LLC (SHINE) request to amend Construction Permit No. CPMIF-001 for the SHINE Medical Isotope Production Facility (SHINE facility) in Rock County, Wisconsin. The approved amendments extend the latest date for completion of the construction of the SHINE facility from December 31, 2022, to December 31, 2025, and administratively change the name of the construction permit holder from SHINE Medical Technologies, LLC to SHINE Technologies, LLC.

DATES: The Order was issued on November 30, 2022.

ADDRESSES: Please refer to Docket ID **NRC-2022-0180** when contacting the NRC about the availability of information regarding this document. You may obtain publicly available information related to this document using any of the following methods:

- **Federal Rulemaking Website:** Go to <https://www.regulations.gov> and search for Docket ID **NRC-2022-0180**. Address questions about Docket IDs in Regulations.gov to Stacy Schumann; telephone: 301-415-0624; email: Stacy.Schumann@nrc.gov. For technical questions, contact the individual listed in the "For Further Information Contact" section of this document.

- **NRC's Agencywide Documents Access and Management System**

(ADAMS): You may obtain publicly available documents online in the ADAMS Public Documents collection at <https://www.nrc.gov/reading-rm/adams.html>. To begin the search, select "Begin Web-based ADAMS Search." For problems with ADAMS, please

contact the NRC's Public Document Room (PDR) reference staff at 1-800-397-4209, 301-415-4737, or by email to PDR.Resource@nrc.gov. The SHINE request to amend Construction Permit No. CPMIF-001 is available in ADAMS under Accession No. ML22091A093.

- **NRC's PDR:** You may examine and purchase copies of public documents, by appointment, at the NRC's PDR, Room P1 B35, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852. To make an appointment to visit the PDR, please send an email to PDR.Resource@nrc.gov or call 1-800-397-4209 or 301-415-4737, between 8:00 a.m. and 4:00 p.m. Eastern Time, Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Holly Cruz, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-1053; email: Holly.Cruz@nrc.gov.

SUPPLEMENTARY INFORMATION: The text of the Order is attached.

Dated: December 5, 2022.

For the Nuclear Regulatory Commission.

Joshua M. Borromeo, Chief,
Non-Power Production and Utilization
Facilities Licensing Branch,
Division of Advanced Reactors and Non-
Power Production and Utilization Facilities,
Office of Nuclear Reactor Regulation.

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

In the Matter of)	
)	
SHINE Medical Technologies, LLC)	Docket No. 50-608
)	Construction Permit No. CPMIF-001
(SHINE Medical Isotope Production Facility))	

ORDER

I.

SHINE Medical Technologies, LLC (SHINE, licensee, permit holder) is the holder of Construction Permit (CP) No. CPMIF-001, which the U.S. Nuclear Regulatory Commission (NRC, the Commission) issued on February 29, 2016 (Agencywide Documents Access and Management System (ADAMS) Package Accession No. ML16041A473), for the construction of the SHINE Medical Isotope Production Facility (SHINE facility) in Rock County, Wisconsin. CP No. CPMIF-001 includes December 31, 2022 as the latest date for completion of the construction of the SHINE facility and expires on the latest date of completion. The SHINE facility is currently under construction.

By letter dated April 1, 2022 (ML22091A093), SHINE submitted to the NRC a license amendment request in accordance with section 50.90, "Application for amendment of license, construction permit, or early site permit," of title 10 of the *Code of Federal Regulations* (10 CFR) and 10 CFR 50.55(b). The license amendment request seeks to extend the latest date for completion of the construction of the SHINE facility from December 31, 2022, to December 31, 2025, and to change the name of the CP holder from SHINE Medical Technologies, LLC to SHINE Technologies, LLC. SHINE stated that the proposed name change is administrative because it does not involve any transfer of control of the CP or a change to ownership, organization, rights, or liabilities of SHINE.

II.

Upon review of the license amendment request, the NRC staff determined that SHINE had shown good cause for extending the latest date for completion of the construction of the SHINE facility from December 31, 2022, to December 31, 2025 and that the name change of the CP holder from SHINE Medical Technologies, LLC to SHINE Technologies, LLC is administrative in nature. The staff also determined that the license amendment request involves no significant hazards consideration. The staff prepared an environmental assessment and finding of no significant impact for the requested extension of the latest date for completion of construction and published it in the *Federal Register* on November 10, 2022 (87 FR 67965). On the basis of the environmental assessment, the staff concluded that the requested extension will not have a significant effect on the quality of the human environment. The findings set forth above are supported by an NRC staff safety evaluation dated November 30, 2022, which is available at ML22292A319.

III.

Within 60 days after the date of publication of this notice, any persons (petitioner) whose interest may be affected by this action may file a request for a hearing and petition for leave to intervene (petition) with respect to the action. The scope of this order extending the latest date for completion of construction and administratively changing the name of the CP holder and any proceeding hereunder is limited to direct challenges to the CP holder's asserted reasons that show good cause for the extension and to the name change. Petitions shall be filed in accordance with the Commission's "Agency Rules of Practice and Procedure" in 10 CFR part 2. Interested persons should consult a current copy of 10 CFR 2.309. The NRC's regulations are accessible electronically from the NRC Library on the NRC's website at <https://www.nrc.gov/reading-rm/doccollections/cfr/>. Alternatively, a copy of the regulations is available at the NRC's Public Document Room, located at One White Flint North, Room P1 B35, 11555 Rockville Pike, Rockville, Maryland 20852. If a petition is filed, the Commission or a presiding officer will rule on the petition and, if appropriate, a notice of a hearing will be

issued.

As required by 10 CFR 2.309(d), the petition should specifically explain the reasons why intervention should be permitted with particular reference to the following general requirements for standing: (1) the name, address, and telephone number of the petitioner; (2) the nature of the petitioner's right to be made a party to the proceeding; (3) the nature and extent of the petitioner's property, financial, or other interest in the proceeding; and (4) the possible effect of any decision or order which may be entered in the proceeding on the petitioner's interest.

In accordance with 10 CFR 2.309(f), the petition must also set forth the specific contentions which the petitioner seeks to have litigated in the proceeding. Each contention must consist of a specific statement of the issue of law or fact to be raised or controverted. In addition, the petitioner must provide a brief explanation of the bases for the contention and a concise statement of the alleged facts or expert opinion which support the contention and on which the petitioner intends to rely in proving the contention at the hearing. The petitioner must also provide references to the specific sources and documents on which the petitioner intends to rely to support its position on the issue. The petition must include sufficient information to show that a genuine dispute exists with the applicant or licensee on a material issue of law or fact. Contentions must be limited to matters within the scope of the proceeding. The contention must be one which, if proven, would entitle the petitioner to relief. A petitioner who fails to satisfy the requirements at 10 CFR 2.309(f) with respect to at least one contention will not be permitted to participate as a party.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene. Parties have the opportunity to participate fully in the conduct of the hearing with respect to resolution of that party's admitted contentions, including the opportunity to present evidence, consistent with the NRC's regulations, policies, and procedures.

Petitions must be filed no later than 60 days from the date of publication of this

notice. Petitions and motions for leave to file new or amended contentions that are filed after the deadline will not be entertained absent a determination by the presiding officer that the filing demonstrates good cause by satisfying the three factors in 10 CFR 2.309(c)(1)(i) through (iii). The petition must be filed in accordance with the filing instructions in the section of this document discussing electronic submissions (E-Filing).

If a hearing is requested, and the Commission has not made a final determination on the issue of no significant hazards consideration, the Commission will make a final determination on the issue of no significant hazards consideration. The final determination will serve to establish when the hearing is held. If the final determination is that the amendment request involves no significant hazards consideration, the Commission may issue the amendment and make it immediately effective, notwithstanding the request for a hearing. Any hearing would take place after issuance of the amendment. If the final determination is that the amendment request involves a significant hazards consideration, then any hearing held would take place before the issuance of the amendment unless the Commission finds an imminent danger to the health or safety of the public, in which case it will issue an appropriate order or rule under 10 CFR part 2.

A State, local governmental body, Federally recognized Indian Tribe, or agency thereof, may submit a petition to the Commission to participate as a party under 10 CFR 2.309(h)(1). The petition should state the nature and extent of the petitioner's interest in the proceeding. The petition should be submitted to the Commission no later than 60 days from the date of publication of this notice. The petition must be filed in accordance with the filing instructions in the section of this document discussing electronic submissions (E-Filing), and should meet the requirements for petitions set forth in this section, except that under 10 CFR 2.309(h)(2) a State, local governmental body, or Federally recognized Indian Tribe, or agency thereof does not need to address the standing requirements in 10 CFR 2.309(d) if the facility is located within its boundaries. Alternatively, a State, local governmental body, Federally recognized Indian Tribe, or

agency thereof may participate as a non-party under 10 CFR 2.315(c).

If a hearing is granted, any person who is not a party to the proceeding and is not affiliated with or represented by a party may, at the discretion of the presiding officer, be permitted to make a limited appearance pursuant to the provisions of 10 CFR 2.315(a). A person making a limited appearance may make an oral or written statement of his or her position on the issues but may not otherwise participate in the proceeding. A limited appearance may be made at any session of the hearing or at any prehearing conference, subject to the limits and conditions as may be imposed by the presiding officer. Details regarding the opportunity to make a limited appearance will be provided by the presiding officer if such sessions are scheduled.

IV.

All documents filed in NRC adjudicatory proceedings, including a request for hearing and petition for leave to intervene (petition), any motion or other document filed in the proceeding prior to the submission of a request for hearing or petition to intervene, and documents filed by interested governmental entities that request to participate under 10 CFR 2.315(c), must be filed in accordance with the NRC's E-Filing rule (72 FR 49139; August 28, 2007, as amended at 77 FR 46562; August 3, 2012). The E-Filing process requires participants to submit and serve all adjudicatory documents over the internet, or in some cases to mail copies on electronic storage media. Detailed guidance on making electronic submissions may be found in the Guidance for Electronic Submissions to the NRC and on the NRC website at <https://www.nrc.gov/site-help/esubmittals.html>. Participants may not submit paper copies of their filings unless they seek an exemption in accordance with the procedures described below.

To comply with the procedural requirements of E-Filing, at least 10 days prior to the filing deadline, the participant should contact the Office of the Secretary by email at hearing.docket@nrc.gov, or by telephone at 301-415-1677, to (1) request a digital identification (ID) certificate, which allows the participant (or its counsel or representative) to digitally sign submissions and access the E-Filing system for any

proceeding in which it is participating; and (2) advise the Secretary that the participant will be submitting a petition or other adjudicatory document (even in instances in which the participant, or its counsel or representative, already holds an NRC-issued digital ID certificate). Based upon this information, the Secretary will establish an electronic docket for the hearing in this proceeding if the Secretary has not already established an electronic docket.

Information about applying for a digital ID certificate is available on the NRC's public website at <https://www.nrc.gov/site-help/e-submittals/getting-started.html>. Once a participant has obtained a digital ID certificate and a docket has been created, the participant can then submit adjudicatory documents. Submissions must be in Portable Document Format (PDF). Additional guidance on PDF submissions is available on the NRC's public website at <https://www.nrc.gov/site-help/electronic-sub-ref-mat.html>. A filing is considered complete at the time the document is submitted through the NRC's E-Filing system. To be timely, an electronic filing must be submitted to the E-Filing system no later than 11:59 p.m. Eastern Time on the due date. Upon receipt of a transmission, the E-Filing system time-stamps the document and sends the submitter an email notice confirming receipt of the document. The E-Filing system also distributes an email notice that provides access to the document to the NRC's Office of the General Counsel and any others who have advised the Office of the Secretary that they wish to participate in the proceeding, so that the filer need not serve the document on those participants separately. Therefore, applicants and other participants (or their counsel or representative) must apply for and receive a digital ID certificate before adjudicatory documents are filed so that they can obtain access to the documents via the E-Filing system.

A person filing electronically using the NRC's adjudicatory E-Filing system may seek assistance by contacting the NRC's Electronic Filing Help Desk through the "Contact Us" link located on the NRC's public website at <https://www.nrc.gov/site-help/e-submittals.html>, by email to MSHD.Resource@nrc.gov, or by a toll-free call at 1-

866-672-7640. The NRC Electronic Filing Help Desk is available between 9 a.m. and 6 p.m., Eastern Time, Monday through Friday, excluding government holidays.

Participants who believe that they have a good cause for not submitting documents electronically must file an exemption request, in accordance with 10 CFR 2.302(g), with their initial paper filing stating why there is good cause for not filing electronically and requesting authorization to continue to submit documents in paper format. Such filings must be submitted by: (1) first class mail addressed to the Office of the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, Attention: Rulemaking and Adjudications Staff; or (2) courier, express mail, or expedited delivery service to the Office of the Secretary, 11555 Rockville Pike, Rockville, Maryland 20852, Attention: Rulemaking and Adjudications Staff. Participants filing adjudicatory documents in this manner are responsible for serving the document on all other participants. Filing is considered complete by first-class mail as of the time of deposit in the mail, or by courier, express mail, or expedited delivery service upon depositing the document with the provider of the service. A presiding officer, having granted an exemption request from using E-Filing, may require a participant or party to use E-Filing if the presiding officer subsequently determines that the reason for granting the exemption from use of E-Filing no longer exists.

Documents submitted in adjudicatory proceedings will appear in the NRC's electronic hearing docket which is available to the public at <https://adams.nrc.gov/ehd>, unless excluded pursuant to an order of the Commission or the presiding officer. If you do not have an NRC-issued digital ID certificate as described above, click "cancel" when the link requests certificates and you will be automatically directed to the NRC's electronic hearing dockets where you will be able to access any publicly available documents in a particular hearing docket. Participants are requested not to include personal privacy information, such as social security numbers, home addresses, or personal phone numbers in their filings, unless an NRC regulation or other law requires submission of such information. For example, in some instances, individuals provide

home addresses in order to demonstrate proximity to a facility or site. With respect to copyrighted works, except for limited excerpts that serve the purpose of the adjudicatory filings and would constitute a Fair Use application, participants are requested not to include copyrighted materials in their submission.

The attorney for the CP holder is Nathan Schleifer, General Counsel, SHINE Technologies, LLC, 3400 Innovation Court, Janesville, WI 53546.

V.

Accordingly, pursuant to Sections 161b and 161i of the Atomic Energy Act of 1954, as amended; 42 U.S.C. Sections 2201(b) and 2201(i); and 10 CFR 50.90 and 10 CFR 50.55(b), IT IS HEREBY ORDERED that CP No. CPMIF-001 is amended to extend the latest date for completion of the construction of the SHINE facility from December 31, 2022, to December 31, 2025, and to change the name of the CP holder from SHINE Medical Technologies, LLC to SHINE Technologies, LLC.

This order is effective upon issuance.

Dated: NOVEMBER 30, 2022.

FOR THE NUCLEAR REGULATORY
COMMISSION.

/RA/

Caroline Carusone, Deputy Director,
Division of Advanced Reactors and Non-
Power Production and Utilization
Facilities,
Office of Nuclear Reactor Regulation.

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